Histogen Announces Removal of Clinical Hold by FDA for HST-003 IND to Initiate a Phase 1/2 Trial for Knee Cartilage Regeneration

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Trial Initiation Anticipated in Second Quarter 2021

$2M Grant Awarded by the Department of Defense in September 2020 to Support Clinical Development

SAN DIEGO, March 15, 2021 (GLOBE NEWSWIRE) -- Histogen Inc. (NASDAQ: HSTO), today announced that the U.S. Food and Drug Administration ("FDA") has confirmed that the Company satisfactorily addressed all clinical hold questions and can proceed with initiation of the planned Phase 1/2 clinical trial of HST-003 to evaluate the safety and efficacy of human extracellular matrix (hECM:HST-003) implanted within microfracture interstices and the cartilage defect in the knee to regenerate hyaline cartilage in combination with a microfracture procedure. It is anticipated that clinical sites participating in the trial will include: OasisMD in San Diego, CA, The Steadman Clinic in Vail, CO and Walter Reed Medical Center in Bethesda, MD.

"We are pleased to have been able to provide the FDA with a comprehensive response resulting in the removal of the clinical hold so we can initiate development of this important potential treatment," said Richard W. Pascoe, Histogen's President and CEO. "We anticipate initiating the Phase 1/2 trial in the second quarter of 2021 utilizing funding provided by the $2M grant from the Department of Defense."

About HST-003
Histogen's human extracellular matrix, or hECM, is intended for regenerating hyaline cartilage for the treatment of articular cartilage defects with a novel malleable scaffold that stimulates the body's own stem cells. In multiple preclinical models, HST-003 has been shown to regenerate mature cartilage and well vascularized bone, indicating great therapeutic potential in the sports medicine, spinal disc repair, orthopedic, and dental areas. Studies conducted by outside experts have demonstrated that HST-003 is anti-inflammatory, angiogenic, and can stimulate the growth of stem cells in damaged areas to induce tissue regeneration. The most extensive in vivo work in animals has focused on the regeneration of new hyaline cartilage and bone in full thickness knee injuries.

About Histogen
Histogen Inc. is a clinical-stage therapeutics company focused on developing potential first-in-class restorative therapeutics that ignite the body's natural process to repair and maintain healthy biological function. Histogen's innovative technology platform utilizes cell conditioned media and extracellular matrix materials produced by hypoxia-induced multipotent cells. Histogen's proprietary, reproducible manufacturing process provides targeted solutions across a broad range of therapeutic indications including hair growth, dermal rejuvenation, joint cartilage regeneration and spinal disk repair. For more information, please visit www.histogen.com.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and other Federal securities laws. For example, we are using forward-looking statements when we discuss Histogen's future operations and its ability to successfully initiate and complete clinical trials and achieve regulatory milestones and related timing, including those related to commencement of the planned Phase 1/2 clinical trial of HST-003 for regeneration of cartilage in the knee; the nature, strategy and focus of Histogen's business; and the development and commercial potential and potential benefits of any of Histogen's product candidates, including HST-003. Histogen may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Because such statements deal with future events and are based on Histogen's current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Histogen that could differ materially from those described in or implied by the statements in this press release, including: the uncertainties associated with the clinical development and regulatory approval of Histogen's product candidates, including potential delays in the commencement, enrollment and completion of clinical trials such as the planned Phase 1/2 clinical trial of HST-003 for regeneration of cartilage in the knee; the potential that earlier clinical trials and studies of Histogen's product candidates may not be predictive of future results; risks related to business interruptions, including the outbreak of COVID-19 coronavirus, which could seriously harm Histogen's financial condition and increase its costs and expenses; and the requirement for additional capital to continue to advance these product candidates, which may not be available on favorable terms or at all. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including those risks discussed in Histogen's filings with the Securities and Exchange Commission. Except as otherwise required by law, Histogen disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date hereof, whether as a result of new information, future events, or circumstances or otherwise.

The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD 21702, is the awarding and administering acquisition office. The views expressed in this press release are those of the author and may not reflect the official policy or position of the Department of the Army, Department of Defense, or the U.S. Government.

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